
Facsimile Cover Sheet

To: Examiner Humera Sheikh
Company: ART UNIT 1615
Phone: 703-308-2927
Fax: 703-308-7922

From: Wendy Marsh
Company: ZARLEY, MCKEE, THOMTE,
VOORHEES & SEASE
e-mail: marsh@zarley.com
Phone: 515-288-3667
Fax: 515-288-1338

Date: November 26, 2001
**Pages including this
cover page:** 8

Comments: Re: Serial No. 09/437,449

**Examiner - attached please find a proposed Amendment After
Final Rejection for your review which incorporates the changes
we discussed last week. Please let me know if the response is
satisfactory for placing the application in allowable form. Thank
you for your consideration.**

THE DOCUMENTS ACCOMPANYING THIS FACSIMILE TRANSMITTAL COVER SHEET CONTAIN INFORMATION FROM THE LAW FIRM OF ZARLEY, MCKEE, THOMTE, VOORHEES & SEASE WHICH MAY BE CONFIDENTIAL AND/OR LEGALLY PRIVILEGED. THE DOCUMENTS ARE INTENDED ONLY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE ADDRESSEE IDENTIFIED ABOVE. IF YOU ARE NOT THE INTENDED RECIPIENT OR AN AGENT RESPONSIBLE FOR DELIVERING THESE DOCUMENTS TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY REVIEW, DISCLOSURE, COPYING, DISTRIBUTION OR THE TAKING OF ANY ACTION IN RELIANCE ON THE CONTENTS OF THIS TRANSMITTED INFORMATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS FACSIMILE IN ERROR, PLEASE IMMEDIATELY NOTIFY THIS FIRM SO THAT WE CAN ARRANGE FOR THE RETURN OF THE ORIGINAL DOCUMENTS TO US. THANK YOU.

RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE – EXAMINING GROUP 1615
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : KUMAR, Vijay
SERIAL NO : 09/437,449
FILED : November 10, 1999
TITLE : PALATABLE, SUSTAINED RELEASE DRUG GRANULES

Grp./A.U. : 1615
Examiner : Scheikh, H.
Conf. No. :
Docket No. : P04176US0

DRAFT

AMENDMENT AFTER FINAL REJECTION

Assistant Commissioner for Patents
Box: AAF
Washington, D.C. 20231

Sir:

In response to the Office Action dated July 9, 2001, please amend the above-identified application as follows:

In the Claims

Please amend claims 1, 8, 19, and 21-34 as follows:

CERTIFICATE OF MAILING (37 C.F.R. § 1.8(a))

I hereby certify that this document and the documents referred to as enclosed therein are being deposited with the United States Postal Service as First Class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this _____ day of November, 2001.

Wendy K. Marsh

1. (Twice Amended)

A polymer complex for entrapping drug granules comprising:
a complex of polyvinyl acetate phthalate (PVAP); and
polyvinylpyrrolidine (PVP);
said PVAP-PVP complex having bands at about 1657 cm⁻¹ and 1724 cm⁻¹ in the spectrum of
the PVAP-PVP complex.

8. (Twice Amended)

A polymer-entrapped drug comprising:
a drug that is insoluble in organic solvent, but soluble or suspendable in an alkaline solution and
insoluble in aqueous acidic solutions;
a complex of polyvinyl acetate phthalate (PVAP); and
polyvinylpyrrolidine (PVP);
said PVAP-PVP complex having bands at about 1657 cm⁻¹ and 1724 cm⁻¹ in the spectrum of
the PVAP-PVP complex.

Please cancel claims 19 and 21-32.

33. (Amended)

A polymer-entrapped drug comprising:
a drug that is insoluble in organic solvent, but soluble or suspendable in an alkaline solution and
insoluble in aqueous acidic solutions;
said drug being entrapped in a complex of polyvinyl acetate phthalate (PVAP) and
polyvinylpyrrolidine (PVP);
said PVAP-PVP complex having bands at about 1657 cm⁻¹ and 1724 cm⁻¹ in the spectrum of
the PVAP-PVP complex.

Please cancel claim 34.

REMARKS**I. Introduction**

It is respectfully requested that this Amendment After Final Rejection be entered and made of record. It is believed that the following amendments and remarks place the application in a form for allowance. The following amendments and remarks at least place the claims in a better form for appeal. No new matter is presented, as such the amendment is proper under 37 C.F.R. § 1.116.

Claims 1, 2, 4-9, 11-14, 16, and 33 remain in the case. Claims 19, 21-32 and 34 have been canceled.

II. Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 1-2, 4-9, 11-14, 16, 19, and 21-34 were rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that the complex of the claims should be further limited so as to express the unique physical structure of Applicant's PVAP-PVP complex which has been prepared in the instant specification. The Examiner notes that the limitations of claims 31 and 34 express the complex structure of the claimed complex.

Applicant has now amended the claims to include the spectrum bands set forth in claims 31 and 34, now canceled. It is therefore believed that the claims now sufficiently define the unique physical structure of the PVAP-PVP complex. Applicant therefore respectfully requests that this ground of rejection be withdrawn.

III. Claim Rejections - 35 U.S.C. § 103(a)

Claims 19, 21-30, and 32 were rejected under 35 U.S.C. § 103(a) as being obvious over Gupta et al. Drug Development and Industrial Pharmacy (1994) or M.A. Elegakey et al. P.P.S.

434-440 or Takayana Chem. Pharm. Bull. PPS 3921-4926. Applicant has now canceled claims 19, 21-30, and 32, thus rendering this ground of rejection moot.

IV. Conclusion

It is believed the application is in a *prima facie* condition for allowance. Allowance is respectfully requested.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Respectfully submitted,

Wendy K. Marsh, Reg. No. 39,705
ZARLEY, McKEE, THOMTE, VOORHEES
& SEASE
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No. (515) 288-3667
Fax No. (515) 288-1338
CUSTOMER NO: 22885

Attorneys of Record

- wm -

Application No. 09/437,449

**AMENDMENT — VERSION WITH MARKINGS
TO SHOW CHANGES MADE — DO NOT FILE**

In the Claims

Claims 1, 8, 19, and 21-34 were amended as follows:

1. (Twice Amended)

A polymer complex for entrapping drug granules comprising:
a complex of polyvinyl acetate phthalate (PVAP); and
polyvinylpyrrolidine (PVP);
said PVAP-PVP complex having bands at about 1657 cm⁻¹ and 1724 cm⁻¹ in the spectrum of
the PVAP-PVP complex.

8. (Twice Amended)

A polymer-entrapped drug comprising:
a drug that is insoluble in organic solvent, but soluble or suspendable in an alkaline solution and
insoluble in aqueous acidic solutions;
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Claims 19 and 21-32 have been canceled.

33. (Amended)

A polymer-entrapped drug comprising:

a drug that is insoluble in organic solvent, but soluble or suspendable in an alkaline solution and

insoluble in aqueous acidic solutions;

said drug being entrapped in a complex of polyvinyl acetate phthalate (PVAP) and

polyvinylpyrrolidone (PVP);

said PVAP-PVP complex having bands at about 1657 cm⁻¹ and 1724 cm⁻¹ in the spectrum of
the PVAP-PVP complex.

Claim 34 has been canceled.